K011954

SEP 1 9 2001

510(k) Summary

Manufacturer:
Sulzer Orthopedics Ltd.
Grabenstrasse 25
CH 6341 Baar, Switzerland

US Designated Agent:
Sulzer Orthopedics Inc.
9900 Spectrum Drive
Austin, TX 78717
Tel: (512) 432-9900
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Contact:
Bruce Waldon
Regulatory Affairs Specialist

Classification Name:
21 CFR Part 888.3520 – Knee joint femorotibial metal/polymer non-constrained cemented prosthesis.

Common/Usual Name:
Unicompartmental Knee

Trade/Proprietary Name:
Sulzer Orthopedics Allegretto Unicompartmental Knee System

Product Description:

The Allegretto Unicompartmental Knee system consists of a metallic distal femoral resurfacing component and a polyethylene proximal tibial resurfacing component. The device is intended for partial replacement of the articulating surfaces of the knee when only one side of the joint (medial or lateral) is affected due to compartmental primary degenerative or post-traumatic degenerative disease, previous tibial condyle or plateau fractures, deformity or revision of previous arthroplasty. The device is a single-use implant intended for implantation with bone cement.

The femoral resurfacing component employs a symmetrical device design that can be used in left or right orientations. The component also features a radius of curvature to reproduce knee morphology for optimal bone coverage and a better kinematic, and two cruciate pegs to aid in its rotational stability. The femoral component is manufactured from Protasul™-2, a CoCrMo alloy that conforms to ISO standard 5832-4 and ASTM F 75.

The femoral component is also available in a distally reinforced version that is identical to the component described above with the exception of an additional 2mm buildup of material on the distal portion of the component. This additional material provides a better fit for patients with pronounced wear of the femoral condyle due to aseptic necrosis, revision, or dysplasia (valgus gonarthrosis).

The tibial component is manufactured from Sulene™-PE, an Ultra-High Molecular Weight Polyethylene (UHMWPe) that conforms to ISO 5834-1,2 and ASTM F 648. The all-polyethylene tibial component features universal geometry that allows it to be used in left and

right knee applications. The superior articulating surface is basically flat, with a slight articulating surface curve to increase the bearing surface of the femoral component. A recessed groove pattern on the inferior surface of the device assists in fixation with bone cement. In addition, radiolucent wire is molded into the poly to assist in radiographic location.

Intended Use/Indications for Use:

The Allegretto Unicompartmental Knee system is intended to replace the medial or lateral compartment of the femorotibial knee joint, damaged as a result of non-inflammatory joint disease or trauma.

The system is an intermediate solution between osteotomy and a total prosthesis, and is indicated in cases of predominantly unicompartmental degeneration in which there is a fairly intact capsular ligament (CL) system.

The Allegretto Unicompartmental Knee system is indicated for use in treatment of:

1. Unicompartmental noninflammatory degenerative joint disease (NIDJD), e.g. avascular necrosis, osteoarthritis and arthritis secondary to a variety of diseases and anomalies.

2. Passively correctable valgus-varus deformity and moderate flexion contracture.

3. Those patients with failed previous surgery where pain, deformity or dysfunction persists.

Substantial Equivalence:

The substantial equivalence of this device is based on equivalence to predicate devices in intended use/indications for use, materials, design, and operational principles. The Allegretto's design and operational principles as a non-constrained unicompartmental knee are similar to the Stryker Howmedica Osteonics SCR Unicompartmental Knee and the Sulzer Orthopedics Natural Knee Uni Knee. The device's intended use and materials are similar to the predicates mentioned, as well as the Styker Howmedica Osteonics PCA and Minimally Invasive Uni Knees, the Biomet Repicci II and Genus Uni Knees, the Smith & Nephew Genesis Uni Knee, the J & J Depuy PFC Uni Knee, and the Zimmer Miller/Galante Uni Knee.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 9 2001

Mr. Bruce Waldon
Regulatory Affairs Specialist
Sulzer Orthopedics Inc.
9900 Spectrum Drive
Austin, Texas 78717

Re: K011954
Trade Name: Sulzer Orthopedics Allegretto Unicompartmental Knee
Regulatory Class: II
Regulation Number: 888.3520
Product Code: HSX
Dated: June 21, 2001
Received: June 22, 2001

Dear Mr. Waldon:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Susan Walter, MS

for

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K 1 1954

Device Name: Allegretto Unicompartmental Knee

Indications for Use:

The Allegretto Unicompartmental Knee consists of a distal femoral resurfacing component and a proximal tibial resurfacing component. It is intended to replace the medial or lateral component of the femorotibial knee joint, damaged as a result of non-inflammatory joint disease, or trauma. The device is a single-use implant intended for cemented use only.

The Allegretto Unicompartmental Knee system is indicated for use in treatment of:

1. Unicompartmental noninflammatory degenerative joint disease (NIDJD), e.g. avascular necrosis, osteoarthritis and arthritis secondary to a variety of diseases and anomalies.

2. Passively correctable valgus-varus deformity and moderate flexion contracture.

3. Those patients with failed previous surgery where pain, deformity or dysfunction persists.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-The-Counter Use**

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011954